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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,583	03/15/2007	Willem Jan Bastiaan Van Wamel	ARSI-012	6152

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EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	**PAPER NUMBER**
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,583	VAN WAMEL ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) *5-7, 21-38, 40-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,8-20,39,50 and 51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *9-10-2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2X 2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response filed 5-20-10 has been entered into the record.

Drawings

The drawings in this application have been accepted. No further action by Applicant is required.

Specification

The disclosure is objected to because of the following informalities:

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Information Disclosure Statement

The information disclosure statements filed 8-21-07 and 8-29-07 have been considered.

Election/Restrictions

Applicant's election without traverse of Group 1, species SEQ ID NO:1 in the response filed 5-20-2010 is acknowledged.

Claims 1-4, 8-20, 39, 50 and 51 are under examination. Claims 5-7 are withdrawn as drawn to non-elected species. Claims 21-38, 40-49 are withdrawn from consideration as drawn to non-elected inventions.

Claim Objections

Claims 1-4, 8-20, 39, 50 and 51 are objected to because of the following informalities:

Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted). Applicants are directed to MPEP 2173.05(s). In the instant case references to figures are inappropriate since there is a practical means of defining the invention by amino acid sequence. Appropriate correction is required.

Claims 12-20, 39, 50 and 51 are objected to as lacking an article at the beginning of the sentence. Correction of form is requested.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 15, 50 and 51 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The contemplated intended use of the nucleic acid is for gene therapy. As such the non-purified, non-isolated recombinant host cell or organism necessarily reads on a human

recipient of the gene therapy and therefore does not constitute statutory subject material.

Double Patenting

Applicant is advised that should claim 1 be found allowable, claim 39 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The claim 39 merely recites the intended use of the nucleic acid of claim 1 and therefore does not structurally limit the nucleic acid of claim 1 and as such claim 1 and claim 39 are identical in scope.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 51 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites a recombinant host cell or organism comprising a bacteriophage. A recombinant host cell or organism cannot comprise a bacteriophage because the skilled artisan defines and describes bacteriophages as infective components of bacteria. Bacteriophages inject nucleic acid into bacteria but the bacteria/host cell/organism do not comprise the bacteriophage per se. Lysogenic phages of temperate bacteriophages when

incorporated into the bacterial DNA are conventionally called prophages. Inasmuch as the claims do not utilize conventional terminology according to basic microbiology or molecular biology, the metes and bounds of the recombinant host cell or organism comprising a bacteriophage cannot be readily ascertained by the skilled artisan since a bacteriophage does not conventionally reside within the recombinant host cell or organism. The specification does not redefine the term in any specific means such that the skilled artisan would be able to interpret the metes and bounds of the claimed subject matter.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 8, 9, 10, 11, 12, 13, 15, 16, 17, 18, 39 and 50 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Chiron et al (02/094868, published 11-28-2002).

Chiron teaches *S. aureus* polynucleotides and polypeptides as well as diagnostic and therapeutic uses thereof. The polynucleotide sequence of SEQ ID NO:1327 is 99% identical as compared with SEQ ID NO:1 and encodes a polypeptide (SEQ ID NO:1101) that is 100% identical as compared to SEQ ID NO:2, described in the specification as a lectin pathway inhibitor (LPI) see Figure 2a. Therefore, Chiron anticipates claims 1-4, 8, 9, 10, 11 and 39. Chiron also teaches methods for recombinant production of the nucleic acids encoding proteins including vectors comprising the nucleic acids (e.g. cloning or expression vectors) and host cell transformed with the vectors (page 3, lines 5-6; page 8, line 25 to page 20, line 34). Chiron teaches process of production of the protein by means of expression by culturing a host cell of the invention under conditions which induce protein expression (see page 4, lines 24-25 and page 8, line 25 to page 20, line 34). Chiron teaches that tine invention will employ conventional techniques of molecular biology, microbiology, recombinant DNA and immunology which are well within the skill of the art (page 7, lines 20-32). As such, Chiron anticipates claims 12, 13, 15, 16, 17, 18 and 50.

Claims 14 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiron et al (02/094868, published 11-28-2002) in view of Christensen (Molecular Biotechnology, 17:219-224, 2001).

Chiron teaches *S. aureus* polynucleotides and polypeptides as well as diagnostic and therapeutic uses thereof. The polynucleotide sequence of SEQ ID NO:1327 is 99% identical as compared with SEQ ID NO:1 and encodes a polypeptide (SEQ ID NO:1101) that is 100% identical as compared to SEQ ID NO:2, described in the specification as a lectin pathway inhibitor (LPI) see Figure 2a. Chiron also teaches methods for recombinant production of the nucleic acids encoding proteins including vectors comprising the nucleic acids (e.g. cloning or expression vectors) and host cell transformed with the vectors (page 3, lines 5-6; page 8, line 25 to page 20, line 34). Chiron teaches process of production of the protein by means of expression by culturing a host cell of the invention under conditions which induce protein expression (see page 4, lines 24-25 and page 8, line 25 to page 20, line 34). Chiron teaches that tine invention will employ conventional techniques of molecular biology, microbiology, recombinant DNA and immunology which are well within the skill of the art (page 7, lines 20-32). Chiron teaches that the staphylococcus nucleotide sequences can be expressed in a variety of different expression systsms, for example those used with mammalian cells, baculoviruses, plants, bacteria and yeast. Chiron differs by not teaching bacteriophage cloning and expression vectors.

Christensen teach that bacteriophage lambda has been used as a cloning vector for over 25 years and has been extensively used as an expression vector. Christensen teach conventional means of expression and cloning of genes in lambda. Christensen teach that lambda vectors can be used for production and purification of proteins in E. coli (see page 219, column 1, first paragraph and abstract).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to insert the nucleic acids of Chiron in the bacteriophage lambda cloning or expression vectors in the art and use such to express proteins in *E. coli*

as referenced by Christensen because Chiron teaches that time invention will employ conventional techniques of molecular biology, microbiology, recombinant DNA and immunology which are well within the skill of the art for expression and that staphylococcus nucleotide sequences can be expressed in a variety of different expression systems.

Claims 16, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiron et al (02/094868, published 11-28-2002) in view of Zhang et al (Gene, 255:297-305, 2000).

Chiron teaches *S. aureus* polynucleotides and polypeptides as well as diagnostic and therapeutic uses thereof. The polynucleotide sequence of SEQ ID NO:1327 is 99% identical as compared with SEQ ID NO:1 and encodes a polypeptide (SEQ ID NO:1101) that is 100% identical as compared to SEQ ID NO:2, described in the specification as a lectin pathway inhibitor (LPI) see Figure 2a. Chiron also teaches methods for recombinant production of the nucleic acids encoding proteins including vectors comprising the nucleic acids (e.g. cloning or expression vectors) and host cell transformed with the vectors (page 3, lines 5-6; page 8, line 25 to page 20, line 34). Chiron teaches process of production of the protein by means of expression by culturing a host cell of the invention under conditions which induce protein expression (see page 4, lines 24-25 and page 8, line 25 to page 20, line 34). Chiron teaches that tine invention will employ conventional techniques of molecular biology, microbiology, recombinant DNA and immunology which are well within the skill of the art (page 7, lines 20-32). Chiron teaches that the staphylococcus nucleotide sequences can be expressed in a variety of different expression systsms, for example those used with mammalian cells, baculoviruses, plants, bacteria and yeast. Chiron differs by not teaching *S. aureus* strains as a cloning and expression vector.

Zhang et al teach gene expression systems for use in the bacterial pathogen *S. aureus* (see abstract and page 298, column 1 to page 299, column 1).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to insert the nucleic acids of Chiron in the cloning or expression vectors in the art and use such to express proteins in *S. aureus* either heterologous or a homologous strain as described by Zhang et al because Chiron teaches that time invention will employ conventional techniques of molecular biology, microbiology, recombinant DNA and immunology which are well within the skill of the art for expression and that staphylococcus nucleotide sequences can be expressed in a variety of different expression systems.

Status of the Claims

Claims 1-4, 8-20, 39, 50 and 51 stand rejected. All other claims are withdrawn from consideration.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-Th 6:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor Robert Mondesi can be reached at 571-272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/
Primary Examiner